#### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS GALVESTON DIVISION

MICHAEL BAZZREA, et al	§	
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Plaintiffs,	§	
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<b>V</b> •	§	Case No. 3:22-cv-00265
	§	
LLOYD AUSTIN, III, et al.,	§	
	§	
Defendants.	§	

#### PLAINTIFFS' REPLY BRIEF

#### **ARGUMENT**

#### I. DEFENDANTS' EVIDENCE DOES NOT SUPPORT POLICY.

Plaintiffs do not ask this Court to act as an epidemiologist or immunologist; nor do Plaintiffs ask this Court to referee a battle of the experts because Defendants have not provided any expert witness testimony. Plaintiffs simply ask that this Court do what Courts do every day—make reasonable determinations on the relevance of Defendants' unsupported statements—and whether that evidence actually supports their policies. These uncited studies cannot be verified by Plaintiffs or the Court and cannot be considered as incorporated by reference.

Defendants have provided no evidence that bears on the questions before this Court that must be answered to adjudicate Plaintiffs' claims. The relevant questions for Plaintiffs' claims, under either RFRA strict scrutiny review or more deferential review for APA claims, are: what are the marginal risks and benefits, for both the service member and the military – in terms of readiness and other asserted compelling interests – of the mandated two-dose regimen for largely healthy, young service members under current circumstances... namely now, in mid-2022, more than 2 years into the "Emergency," with respect to the currently prevalent Omicron sub-variants of Covid-19, when 98% of other service members are fully vaccinated. The risks and benefits of the two-dose regimen must also be compared with the protection provided by: (a) previous documented infections (*i.e.*, natural immunity); (b) alternative mitigation measures; (c) currently available post-infection treatments such as Paxlovid, monoclonal antibodies, and (d) *vigorous exercise*, an unquestionably beneficial and efficacious prophylaxis that military service requires of its youthful cohort.

All of the above information is readily available to the Defendants Department of Defense ("DOD"), the U.S. Coast Guard ("USCG"), the Department of Homeland Security ("DHS"), and the Food and Drug Administration ("FDA"). The Defendants are unquestionably the governmental agencies "textually committed to resolving ... scientific debates" by bringing to bear the United States governments' unmatched "scientific, economic, and technological resources" in military and medical matters. *Navy SEAL 1 v. Austin*, 2022 WL 1294486, at \* 6 (D.D.C. Apr. 29, 2022) ("*Navy SEAL 1*"). Yet despite having the full resources of the United States government and ready access to comprehensive health data for service members, Defendants have deliberately chosen *not* to provide relevant

data. Not only that, they have intentionally chosen to obfuscate and denigrate the systems in place that could show if these shots are efficacious or not. Their choice to both omit information and attack their own data and systems, and to selectively ignore expert, mandatory guidance from the CDC reinforces Plaintiffs' claims that Defendants have acted in bad faith.<sup>1</sup>

The table attached as Exhibit 1 demonstrates that the studies referenced by Defendants suffers from one or more—and usually all—of the following defects:

- 1. Historical data from the 2020 and 2021 pre-Omicron, pre-vaccine phase and does not address the present state of 'the force';<sup>2</sup>
- 2. Analysis of general population, rather than for service-members;
- 3. Does not disaggregate by age, weight, BMI, health or medical conditions;
- 4. No citations to a study and cannot be verified or included in record;
- 5. Includes or compares "boosters" to unvaccinated; and/or
- 6. No comparison for natural immunity or non-"vaccine" treatments.

Defendants do not attempt to quantify the relative benefits of vaccination for the asserted compelling interest (*i.e.*, readiness, unit cohesion, lives saved,

<sup>&</sup>lt;sup>1</sup> See, e.g., ECF 17, ¶¶ 3-5. Whistleblowers showed data from the DoD's own Defense Medical Epidemiology Database (DMED) highlighting extraordinary rises in a whole cohort of injuries far above baseline numbers for previous years that raise serious questions about adverse events in military members, particularly involving young women of childbearing age.

<sup>&</sup>lt;sup>2</sup> Colonel Fin. Mgmt. Officer v. Austin, No. 8:22-CV-1275-SDM-TGW, 2022 WL 3643512, at \*16 (M.D. Fla. Aug. 18, 2022) ("CFMO"). Defendants state that 96 service members have died from COVID but only two were "fully vaccinated." Opp. at 3. But they do not identify when these deaths occurred. Defendants do not tell us how many of these deaths were in 2020 before any vaccines were available, or how many were in 2021 before Mandate was adopted or implemented.

reductions in days lost from sickness, quarantine or hospitalization) compared to non-vaccination, and completely ignores the immense costs from the loss of highly trained and experienced service members. Defendants have the data and expertise needed to make meaningful comparisons, but this Court cannot defer to Defendants' expertise or judgment where they have altogether refused to exercise it, or if they have, refused to provide any relevant data demonstrating that they have applied their vast expertise and resources to the specific problem at hand.

Plaintiffs respectfully submit that the relevant, undisputed evidence that this Court should consider are the following: First, no active-duty service member, whether vaccinated or not, has died since November 2021 when the Omicron variant became prevalent. See ECF 22-2, Rans Decl., at 12-13 & Table. Second, the Defendants' own data shows that the treatment for the virus has killed more service members (119), see ECF 17, ¶ 5, than the virus itself (96). Opp. at 25. Third, the Centers for Disease Control and Prevention ("CDC") has determined that the mandated two-dose regimen provides "minimal protection against infection and transmission," ECF 17-6, CDC Guidance, at 1, and recommends "no longer differentiat[ing] based on vaccination status." Id. at 3. Fourth, the FDA authorized new "bivalent" vaccines because the licensed vaccines are not available or adequate for treating Omicron, and the CDC will purchase the new "bivalent" vaccines for both primary series and boosters going forward. See infra Section II.B.

#### II. THIS COURT HAS SUBJECT MATTER JURISDICTION

### A. Plaintiffs' Claims and Relief Sought Are Justiciable.

Congress has "plenary authority" ... 'To make Rules for the Government and Regulation of the land and naval Forces." *Chappell v. Wallace*, 462 U.S. 296, 301 (1982) (*quoting* U.S. Const. Art. I, § 8, cl. 14). "By enacting RFRA, Congress exercised this plenary authority to guarantee the 'broad protection for religious liberty." *CFMO*, 2022 WL 3643512, at \*7 (*quoting Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 706 (2014)). "To ensure comprehensive protection of Free Exercise," *id.*, at \*6, RFRA allows "[a] person whose religious exercise has been burdened in violation of this section" to "assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." 42 U.S.C. § 2000bb-1(c).

RFRA was enacted with "singularly bi-partisan support," CFMO at \*6, for the express purpose of "restor[ing] ... the protection for Free Exercise suddenly eroded by the Supreme Court in" *Employment Division v. Smith*, 494 U.S. 872 (1990). *CFMO*, 2022 WL 3643512, at \*6. As such, "RFRA warrants heightened and focused attention and diligent compliance by the government, including the military, and discerning enforcement by the courts." *Id*. RFRA applies to "everyone from the President to a park ranger, ... from the Chairman of the Joint Chiefs of Staff to a military recruiter." *Id*., at \*6.

Plaintiffs' claims and requested relief are not barred by the Supreme Court's

decision in *Navy SEALs 1-26 v. Austin*, 142 S.Ct. 1301 (2022). *See* Opp. at 18, 30. The majority's decision left intact the district court's and the Fifth Circuit's determinations that RFRA claims largely identical to Plaintiffs were justiciable, ripe, and met all requirements for granting a preliminary injunction. Instead, the majority limited the scope of injunctive relief for Navy SEALs and Naval Special Warfare operators, who are the sharpest tip of the spear (or rather trident) and unquestionably the "elite of the elite of this country's special operations forces." *Navy SEAL 1*, 2022 WL 1294486, at \* 2. The Supreme Court was certainly aware of the clandestine nature of that work, need for worldwide deployability at a moment's notice, and other uniquely demanding requirements for the Nation's special operations forces.<sup>3</sup> These factors do not apply to the vast majority of military specialties, including Coast Guard Plaintiffs, who are not special forces.<sup>4</sup>

<sup>&</sup>lt;sup>3</sup> See, e.g., Navy SEAL 1, 2022 WL 1294486, at \*6 (concluding that Navy SEAL's claim would "require the Court to review the missions to which Plaintiff has been assigned in the recent past, the tactical particulars of those missions, and whether those tactical particulars are reflective of future special-operations missions to which Plaintiff would be assigned in the future. The tactical necessities of a particular mission are perhaps the epitome of 'complex, subtle, and professional decisions' otherwise left to the Commander-in-Chief and their subordinates.")(citation omitted).

<sup>&</sup>lt;sup>4</sup> This "non-binding, shadow docket decision," *Navy SEAL 1*, at \*4, did not purport to go beyond the facts of, or specific parties to, the case, much less to announce a broader "military non-justiciability" doctrine articulated in Justice Kavanaugh's "concurring" opinion, as Defendants' claim. *See* Opp. at 18 & 30. Justice Kavanaugh was only speaking for himself, as no other Justice joined his opinion. In fact, his solo opinion appears to be a dissent because it was contrary to the majority's decision in concluding that "RFRA does not justify judicial intrusion into military affairs in this case." *Austin*, 142 S.Ct. at 1302 (Kavanaugh, J., Concurring). Justice Kavanaugh's approach would have required dissolution of the injunction in its entirety, rather than trimming it back around the edges.

## B. Defendants Do Not Have Comirnaty, But Even If They Did, It Would Not Deprive Court of Jurisdiction.

Defendant DOD claims to have obtained a limited quantity of FDA-licensed and labeled Comirnaty more than nine months after the Comirnaty was licensed and the DOD Mandate was announced. (Defendants do not claim to have any FDA-licensed Spikevax.) Plaintiffs and counsel have attempted to verify that the DOD has actually obtained the FDA-licensed product that is labeled in accordance with the statutory and regulatory requirements and manufactured in accordance with the applicable Biologics License Application ("BLA").

Military whistleblowers, including prospective Plaintiff USCG LT Chad Coppin, have inspected the "Comirnaty-labeled" vials and lot numbers. The vials available are *not* FDA-approved Comirnaty. Instead, they are Emergency Use Authorization ("EUA") products (from Lot FW1331, an EUA lot) that were *not* manufactured in accordance with the BLA or at BLA-approved locations and therefore are *not* the FDA-licensed product they purport to be. *See* Ex. 2, Aug. 18, 2022 Letter from Sen. Ron Johnson to DOD, FDA and CDC, at 1-2. The FDA has not responded to Senator Johnson, but in related litigation, the FDA claims that these lots were manufactured in Kalamazoo, Michigan. The attached declaration of LT Coppin shows that Kalamazoo was not a BLA-approved location for this lot at the time it was manufactured on January 28, 2022, nor when it was shipped in April 2022, *see* Ex. 3, Coppin Decl., ¶¶ 5-8. The Defendants continue their policy of offering what Defendant DOD and its lawyers believe they can argue are "good"

enough" substitutes – with no statutory bio-equivalency approvals or determinations ever having been made – *in lieu of* an actual licensed product, which remains legally unavailable by statutory declaration of Defendant FDA.<sup>5</sup>

Even if Defendants had FDA-licensed Comirnaty, Defendants' offer has no impact on Plaintiffs' claims or the jurisdiction of this Court as all Plaintiffs' injuries alleged in the Complaint – including the religious discrimination they've suffered throughout the Coast Guard's sham accommodation policy – occurred during the period when the DOD unlawfully mandated EUA vaccines and Defendant DOD and USCG have disciplined Plaintiffs (and discharged similarly-situated class members) for refusal to take EUA vaccines.<sup>6</sup> Further, there are not and never have been sufficient quantities of Comirnaty for un- or partially-vaccinated members.<sup>7</sup>

Accordingly, Defendants' offer does not affect Plaintiffs' standing because it

<sup>&</sup>lt;sup>5</sup> It is Plaintiffs' position that Defendant DOD cannot legally offer a legally unavailable vaccine and if, in fact, a "licensed vaccine" is available, then the EUAs for other equivalent products must terminate as a matter of law, under 21 USC §360bbb-3. The "unavailability" of Comirnaty is the sole basis for FDA's continued issuances and reissuances of EUAs for unlicensed products to be used. Plaintiffs believe any military member offered Comirnaty has a right to ask for summary judgment terminating the other EUAs.

<sup>&</sup>lt;sup>6</sup> Plaintiffs have responded to Defendants' offer to take "Comirnaty-labeled" product. *See* Ex. 4, DOJ Email Exchange.

<sup>&</sup>lt;sup>7</sup> The DOD claims to have received a total of 42,000 doses, which first become "available for ordering" in May 2022. ECF 22-2, Rans Decl., ¶ 19. Defendants do not state how much, if any, is currently available. Assuming the full amount is still available (42,000 doses), this is sufficient for 21,000 service members. There are at least 25,000 unvaccinated service members who filed RARs, see Compl., ¶ 61 & Table 1, and an additional 90,000 partially vaccinated DOD personnel. See DOD, Coronavirus: DOD Response, DOD Vaccination Data (Table), available at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/ (last visited Sept., 4, 2022). The existing supply is sufficient for 25-30% of this number, meaning that up to 75% would be required to take an EUA vaccine.

does nothing to eliminate or redress Plaintiffs' existing injuries due to noncompliance with the unlawful order to take an EUA vaccine. Nor will it preclude any future injuries because the DOD has not rescinded nor altered its policy, and due to the insufficient quantities available, the vast majority of Plaintiffs and class members would have to take an EUA vaccine to comply with the Mandate. Plaintiffs are entitled to a ruling on their declaratory judgment claim with regard to these unlicensed products, and specifically to the DOD and FDA's legal insistence in written policy that together they have the authority to compel the administration of unlicensed, substitute (EUA) products in place of licensed products to military members without a Presidential waiver of informed consent.

The DOD adopted the Pfizer Interchangeability Directive September 14, 2021, just three weeks after the DOD Mandate. *See* ECF 1-7. DOD repeated this illegal policy on May 3, 2022, when it adopted the Moderna Interchangeability Directive. *See* ECF 1-8. On August 31, 2022, the FDA granted an EUA for the Pfizer and Moderna "bivalent vaccines" as booster shots for treatment of the currently prevalent Omicron sub-variants.<sup>8</sup> On August 16, 2022, the CDC announced that the U.S. Government would procure 175 million doses of the bivalent vaccines for

<sup>&</sup>lt;sup>8</sup> In the new EUAs, the FDA continues to assert that the approved vaccines are unavailable (*i.e.*, "not sufficient approved vaccine available") and further indicate that the approved product is not adequate for treating Omicron (*i.e.*, no approved vaccine "that contain or encode the spike protein of the Omicron variant." Ex. 5, Aug. 31, 2022 Pfizer Bivalent EUA Letter, at 14 n.30; Ex. 6, Aug. 31, 2022 Moderna Bivalent EUA Letter, at 13 n.21.

a fall/winter campaign for both "primary" series and "booster" shots. *See* Ex. 7, Aug. 16, 2022 CDC Planning Guide, at 1. The discussion of using the "bivalent" vaccines for the "primary" series indicates that the government will likely find that the bivalent vaccines are "interchangeable" with, or may be used "as if", they were FDA-licensed vaccines for primary series or booster that could be mandated for service members like Plaintiffs.9 Accordingly, the FDA and Defendants are repeating the alleged unlawful conduct every few months, which is insufficient time for a court to adjudicate the merits.

#### C. Plaintiffs Have Standing.

Defendants erroneously assert that Plaintiffs lack standing as to their claims against the FDA. <sup>10</sup> In *Children's Health Defense Fund v. FDA*, however, the Court found that the Plaintiffs failed to show causation and redressability from the *sole defendant*, the FDA, which led to the court's decision that plaintiffs' injuries from the DOD Mandate resulted from "the independent action of some third party [*i.e.*, DOD] **not before the court**[.]" *CHD*, 2022 WL 2704554, at \*3 (emphasis added). Here, all of the agencies necessary to grant

<sup>&</sup>lt;sup>9</sup> It appears that military members can now expect to license their own immune system from the government, with periodic updates at bureaucratic whim.

<sup>&</sup>lt;sup>10</sup> See Opp. at 13 (citing Children's Health Defense Fund v. FDA, 2022 WL 2704554 (6th Cir. July 12, 2022) ("CHD"). CHD II holds that the DOD "can require vaccination regardless of whether the vaccine is distributed pursuant to a license or EUA." CHD II, at \*4. This is incorrect on its face − 10 U.S.C. § 1107a expressly prohibits the DOD from mandating EUA treatments; it does not purport to address distribution. The court's statement was driven by the fact that DOD was not a party and is therefore necessarily dicta.

Plaintiffs relief are parties to this proceeding.

With respect to traceability and redressability, the FDA's actions—the FDA Interchangeability Determination and FDA Waiver, *see* Mot. at 10 & n.14—are the proximate and "but for" cause of the DOD's EUA Mandate. The DOD Mandate permits only FDA-licensed and labeled vaccines to be mandated; without the challenged FDA actions, which convert an unlicensed product to a licensed one, the DOD could not have mandated EUA vaccines. An order against the FDA can redress those injuries and stop the Mandate itself because, as shown above and in the Coppin Declaration, the Defendants do *not* have Comirnaty.

### D. Plaintiffs' Claims Are Ripe.

Plaintiffs here challenge an inter-related series of discrete, final, and coordinated agency actions adopting generally applicable rules, regulations, and policies that: (1) represent the consummation of the agency's decision-making process; (2) have been consistently implemented since the adoption of the DOD Mandate through the present; (3) determine Plaintiffs' legal rights and obligations; and (4) are the legal basis and proximate cause for Plaintiffs' injuries. *See* Mot. at 10-13 & 24-25.

Defendants seek to conflate the fitness criteria (finality, definiteness, need to develop factual record) with the injury analysis. The challenged agency actions are *generally* applicable rules that have been directly applied to, and enforced against, Plaintiffs, and more than 1,400 similarly-situated class members, in

exactly the same way. They are now purely "legal question[s]" ripe for review that "will foster rather than impede final resolution of this matter." *State of La. v. Dept. of Energy*, 507 F.Supp.1365, 1374 (W.D. La. 1981). The court need not await completion of individual administrative proceedings, which are not challenged, to rule on the Plaintiffs' claims.

Plaintiffs' past and ongoing injuries easily satisfy the hardship prong. *See* Mot., ¶ 12 (summarizing Plaintiff injuries), and Section II.E. *infra*. Plaintiffs face the imminent threats of separation proceedings, discharge, forced retirement, or placement on the ISL (Inactive Status List). Defendants have not agreed to pause these proceedings while this matter is briefed by the Court and will discharge one of the named Plaintiffs if relief is not granted. If the PI Motion is denied, all remaining Plaintiffs will be discharged as well.

#### E. Bazzrea's and Cheatum's Claims Are Not Moot.

Bazzrea's and Cheatum's claims have not been mooted by having been compelled to receive the shots under duress over their strong and sincerely held religious objections. *See* Compl., ¶¶ 13 (Bazzrea) & 19 (Cheatum). Indeed, Bazzrea and Cheatum's claims are the strongest of all: both have genuine religious objections to these shots, but because of the Defendants unrelenting and illegal pressure, they both finally succumbed and violated their own consciences.¹¹ The

<sup>&</sup>lt;sup>11</sup> See, e.g., Ex. 8, Suppl. Decl. of Master Chief Bazzrea.

government somehow concludes that its illegal and coercive arm-twisting provides a legal windfall – woe betide the victim who capitulates! Defendants knowingly, willfully, and repeatedly violate every Plaintiffs' RFRA rights.

The Defendants *inter alia* threatened all of the Plaintiffs' promotion/rank, current and future pay (retirement), immediate and future health insurance for themselves and their families, loss of earned benefits (such as GI Bill), recoupment of any enlistment bonuses, simultaneously deprived them of their liberty, freedom of movement, etc., made them (alone) wear masks on base to visually identify them to everyone on base as 'unclean' and non-conforming (in addition to incidentally revealing their personal medical information to the public), and *now* argue to the Court that if a Plaintiff should finally succumb to all of these illegal and coercive tactics that the *Equity* power of this court demands this result in a legal benefit to the *perpetrator*? The Court will search in vain for any historical antecedent in Anglo-American equity jurisprudence to command such a result. Defendants' argument also completely misapprehends the nature of First Amendment claims.

A religious objector suffers a loss of religious exercise when government puts [the objector] to this choice: violate a sincerely held religious belief or face serious disciplinary action. In other words, a RFRA objector's claim ripens — and subjects the RFRA objector to irreparable harm — upon the threat of serious discipline, not upon the realization of the threat.<sup>12</sup>

 $<sup>^{12}</sup>$  CFMO, at \*42, (citations omitted). See also, Steffel v. Thompson, 415 U.S. 452, 459 ("[I]t is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights.")

#### III. PLAINTIFFS HAVE A SUBSTANTIAL LIKELIHOOD OF SUCCESS.

#### A. Plaintiffs Will Prevail on RFRA and Free Exercise Claims.

#### 1. Defendants Have Systematically Denied RARs.

The information publicly available when the Complaint was filed indicated that zero RARs had been granted by the Coast Guard. *See* Compl., ¶ 61 & Table 1. Defendants have provided current data, showing that 12 RARs and RAR appeals have been granted out of 1,343 RARs submitted, *see* ECF 22-8, Ex. A, or just under one percent (1%). Plaintiffs maintain that the real number of RARs remains zero. Several other courts reviewing other Services' RFRA policies have found that the RARs granted by other services are in fact administrative exemptions for those in the final months of service. ¹³ Defendants have not attempted to dispute this claim. The unrebutted evidence before this Court is that the USCG has granted zero RARs.

Even if these 12 approved RAR were valid RARs, rather than disguised administrative exemptions, sub-1% approval rates are more than sufficient to demonstrate "systemic" RFRA violations and to grant Service-wide injunctions like that sought by Plaintiffs here. "[I]t is hard to imagine a more consistent display of discrimination." Moreover, Defendants have done so using the same form letters

<sup>&</sup>lt;sup>13</sup> See, e.g., CFMO, at \*1 (RARs granted only to those "who are due for retirement and prompt separation"); Navy SEAL 1 v. Austin, 2022 WL 534459, at \*19 (M.D. Fla. Feb. 18, 2022) ("MDFL Navy SEAL 1") (same); Poffenbarger v. Kendall, 2022 WL 594810, at \*13 n.6 (S.D. Oh. Feb. 28, 2022) ("Poffenbarger") (same for Air Force).

 $<sup>^{14}</sup>$  Navy SEALs 1-26 v. Austin, 2022 WL 1025144, at \*5 (N.D. Tex. Mar. 28, 2022) (granting

that change only the name and the description of the service members' role, *see* Compl., ¶¶ 89-90, that courts have found to be definitive proof that the Service failed to provide the individualized determination required by RFRA, DODI 1300.17, and the applicable service regulation (here COMDTINST 1000.15).¹⁵ Finally, a Navy Chaplain currently assigned to the Coast Guard is a plaintiff in a separate federal action (*Alvarado v. Austin*) and filed a declaration included here that provides clear and irrefutable evidence of the religious hostility and sham RAR process by Defendant Coast Guard.¹⁶

#### 2. Defendants Discriminate Against Religious Exercise.

Defendants' assertion that religious accommodations are somehow qualitatively different from, and therefore not comparable to, secular medical and administrative exemptions are without merit. *See* Opp. at 27-28. All exemptions are temporary and time-limited. <sup>17</sup> Further, all COVID-19 vaccine accommodations

class-wide PI for Navy); *Doster v. Kendall*, 2022 WL 2760455, at \*4 (S.D. Ohio July 14, 2022) (same for Air Force for <1% approval rate); *CFMO*, 2022 WL 3643512, at \*3 (same for Marine Corps).

<sup>&</sup>lt;sup>15</sup> See, e.g., CFMO, at \*3-4 (describing and quoting Marine Corps form letter for class certification); Doster, at \*6 (same for Air Force); Navy SEALs 1-26, at \*7 (same for Navy).

<sup>&</sup>lt;sup>16</sup> See Ex. 9 (Navy Chaplain LT Justin Brown Suppl. Decl.).

<sup>&</sup>lt;sup>17</sup> See, e.g., ECF 1-4, DOD Instruction 1300.17, Religious Liberty in the Military Services, ¶3.2.g.1 (Sept. 1, 2020) ("an approved accommodation may be subject to review and recission, in whole or in part, at any time" based on change in circumstances); ECF 1-13, COMDTINST 1000.15, ¶11.c.8.a ("An approved accommodation may be subject to review and rescission, in whole or in part, at any time, based upon a determination that the circumstances under which the grant of accommodation was approved have changed …").

are vaccine-specific.18

Plaintiffs have in the past stated that they would be willing to take FDA-approved vaccines to which they do not have religious objections.<sup>19</sup> This, however, does nothing to change the viability of their claims and the claims they assert on behalf of the class. Defendants' have created an impossibly skinny strawman by narrowing complex theological objections to these shots down to "aborted fetal cell tissue" and then claiming to offer a shot that allegedly doesn't have those defects. As it turns out, Novavax used aborted fetal cells (from cell-line HEK-293) for comparison testing of its insect-protein derived vaccine.<sup>20</sup> Regardless, Plaintiff Wadsworth's own words reveal the inadequacy of the government's claim to be able to out-reason religious objections to its mandate.

Finally, Defendants assert that the same restrictions apply to the unvaccinated whether for secular or religious reasons, *see* Opp. at 28. Defendants

<sup>&</sup>lt;sup>18</sup> A medical exemption from the currently FDA-approved vaccines does not exempt a service member from other vaccination requirements. Medical exemptions are available, among other things, to service members who have medical conditions (or contraindications) or severe allergic reactions that are contraindicated for the current vaccines. *See* Opp. at 28 & n.25.

<sup>&</sup>lt;sup>19</sup> See Compl., ¶ 86. Plaintiffs Wadsworth and Wilder initially considered taking Novavax—an EUA vaccine that cannot be mandated—because they had believed it was not developed using aborted fetal cells and was therefore consistent with their religious beliefs. See Opp. at 22; ECF 22-10, Wilder RAR Package, at 22; ECF 22-11, Wadsworth RAR Package, at 564. Wadsworth subsequently discovered through further research that Novavax was in fact developed using aborted fetal cells. See Ex. 10, Wadsworth Supp. Decl., ¶ 16. Wadsworth also notes that after "earnest prayer, hours of intense research" he will continue abstaining from vaccination with Novavax or other currently available COVID-19 vaccines.

 $<sup>^{20}</sup>$  See, e.g., Sarah Quayle, "Yes, Novavax Used HEK293, An Aborted Fetal Cell Line," available here: https://tinyurl.com/mvcshxpy

fail to acknowledge that only those seeking religious accommodation are being systematically discharged, singled-out for calumny, etc., while those with medical exemptions are not. Plaintiffs have alleged that Defendants have violated Plaintiffs' free exercise rights by granting more favorable treatment of comparable secular activities than for religious exercise by the Services collectively granting over 100 times as many secular exemptions as religious accommodations (even assuming counterfactually that they are not disguised administrative exemptions). See Mot. at 25-27 & Table. The Defendants have failed to respond to these allegations and state that the number of secular exemptions is "UNKNOWN" (except for permanent medical exemptions). ECF 22-5, Ex. A. Defendants' choice not to provide this information does not rebut Plaintiffs' allegations, and in the absence of a contrary response, this Court should presume that the pattern of religious vs. secular exemptions for the Coast Guard is consistent with the ratio for the other 3 military service branches so far enjoined.

## 3. The Court Need Not Defer to Defendants' Purpose.

Having met the burden of showing that Defendants have substantially burdened Plaintiffs' free exercise of religion, the burden shifts to Defendants to demonstrate that their policies satisfy strict scrutiny. *See O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 429 (2006). For Free Exercise claims, courts look "beyond facial discrimination," *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 534 (1993) (citations omitted), and the

government's stated purpose to consider the actual purpose and effects. *Id.* at 535 ("[T]he effect of a law in its real operation is strong evidence of its object.").

Defendants' Categorical RAR ban cannot stand, even if the asserted purpose is taken at face value. As explained in the PI Motion, the military stands to lose tens and perhaps hundreds of thousands, *see* Mot., ¶ 8, and the Coast Guard over 1,300, *see* ECF 22-5, Ex. A (1,343 RAR submitted with 12 supposedly granted), by mandating a vaccine (1) that cannot further its stated purpose (2) to protect against a disease that has not killed a single active-duty service member (whether vaccinated or not) since November 2021. *See* ECF 22-2, Rans Decl., at 12-13.

Defendants have also justified their policy based on the asserted need for Coast Guard members must be "worldwide deployable," Opp. at 28 n.26, despite the fact that Plaintiffs and most similarly-situated class members deploy only in the United States or its coastal waters, or not at all. This Court must reject this circular reasoning to justify religious discrimination by claiming that violations are instead based on independent and objective requirements.<sup>21</sup>

<sup>&</sup>lt;sup>21</sup> See, e.g., CFMO, at \*17 (Defendants "cannot evade RFRA by defining the conditions of service to exclude the possibility of an accommodation. This definitional sleight of hand evades the inquiry that RFRA demands: whether the Marine Corps' generalized interest in worldwide deployability is materially impaired by tolerating a few religious objectors and accommodating their continued service to the Marine Corps despite the generalized policy of worldwide deployability."); Harrison v. Austin, 2022 WL 1183767, at \*19 (E.D. Va. Apr. 6, 2022) ("Harrison") (rejecting same circular reasoning for limiting HIV positive service members based on "the only bar to their deployment was [the military's] own regulations, which restrict deployability based on HIV alone.").

# 4. The Court Must Consider the Compelling Interest in Retaining Service Members Who Wish to Serve.

The Court can and must consider more than one "compelling purpose" in evaluating the military's justification, especially when there is strong evidence that the asserted justification is not the actual one motivating the policy. The United States and its citizens have invested trillions of dollars in our service members to provide for our national defense. The military has a compelling purpose in retaining trained, experienced, willing, patriotic service members, and to consider the other side of the ledger in imposing its policy. The military routinely asserts its interest in retaining trained and experienced service members to justify its policies. <sup>22</sup> *CFMO*, at \*17. Even if Defendants' here give this interest no weight, the Court must consider the compelling governmental interest in retention of experienced veterans who wish to continue to serve and the larger interest of U.S. citizens who rely on them for their defense.

## 5. "Gratuitous Restrictions" Show Hostility to Religion.

Defendants have long imposed arbitrary and punitive restrictions on those seeking religious accommodations. *See* Mot., ¶ 12. Such discrimination is based on obsolete science and contrary to CDC guidance to no longer discriminate based on vaccination status, *see* ECF 17-6, Aug. 11, 2022 CDC Guidance. "It is not

<sup>&</sup>lt;sup>22</sup> See, e.g., Harrison, at \*17 (describing DOD interest in retention as one where the military is "incline[d] decidedly toward allow[ing] the member to continue to perform those duties and return the investment the [military] has made in the member.").

unreasonable to infer ... that a law which visits 'gratuitous restrictions' on religious conduct seeks ... seeks not to effectuate the stated government interests, but to suppress the conduct because of its religious motivation." *Church of Lukumi Babalu*, 508 U.S. at 538 (citation and quotation marks omitted).

#### **B. Plaintiffs Will Prevail on Substantive Due Process Claims**

Courts do not defer to an agency that has exceeded its statutory authority and/or violated federal statutes or its own regulations in an "attempt to usurp major policy decisions properly made by Congress," *NLRB v South Cent. Bell Telephone Co.*, 688 F.2d 345, 351 (5th Cir. 1982), or States. Instead, courts review the agency's legal interpretation of the governing statute because such actions are not matters "peculiarly within the agency's expertise and discretion." *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994).

The level of scrutiny is determined by whether the mandated products are treatments, subject to strict or heightened scrutiny, or vaccines and *arguably* subject to rational basis review under *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). Defendants have <u>failed altogether to respond</u> to Plaintiffs' demonstration that the products are not vaccines under Defendants' own regulations, or as that term was understood by the *Jacobson* court. *See* Mot. at 30-31 & ECF 17-1, DOD 6205.02. Plaintiffs should be deemed to have carried their burden of proof on these unrebutted claims, which should conclusively yield a ruling in Plaintiffs' favor.

In Section I and Exhibit 1, Plaintiffs demonstrate that Defendants have not

provided any relevant evidence that bears on the questions before this Court. Defendants' legal interpretation cannot survive even rational basis review once the deference is stripped away. For such major policy decisions, courts apply a more searching, and non-deferential, version of rational basis review in which they independently weigh the evidence and assess whether the action furthers the asserted policy or is instead an improper pretext.<sup>23</sup>

Additionally, Plaintiffs have demonstrated that the stated purposes of "military readiness" and "health and welfare" are pretexts for improper and unlawful motives like religious discrimination, and that Secretary Austin's actions are arbitrary and capricious in violation of the APA. See Compl., ¶¶ 170-183; Mot. at 41-43. The evidence provided here, and in the preceding section, see supra Section III.A, shows that the DOD Mandate and other challenged actions have no rational basis and have precisely the opposite effect of the stated purpose as the "(non)cure" has already killed more service members than the disease it is supposed to treat. Rather than promoting military readiness, continued mandating of these "vaccines" will destroy it, resulting in the loss of hundreds of thousands of service members and threatening the viability of the All-Volunteer Force.

Plaintiffs "argue that the intra-service processes ... are insufficient as a matter of due process." Opp. at 37. Plaintiffs addressed at length the sham RAR

 $<sup>^{23}</sup>$  See, e.g., Harrison, 2022 WL 1183767, at \*12-14 (weighing scientific evidence in finding DOD HIV deployment policy failed rational basis review).

process that amounts to little more than theater with a pre-determined outcome. See Compl., ¶ 156 & Mot. at 17-18 (futility of RAR process). The subsequent processes like the BCMR are equally futile and in any case are not empowered to set aside a Service regulation, particularly where relief would require the Service Secretary himself to determine that his own policy is an "error" or "injustice." See Mot. at 18. Contrary to Defendants' erroneous assertion, Opp. at 36, Plaintiffs have identified the protected life, liberty, and property interests, as well as fundamental First Amendment rights, of which they already have been deprived by the Defendants' actions throughout the RAR charade. See Compl., ¶¶ 154-157 & Mot. at 34.

#### C. Plaintiffs Will Prevail on Informed Consent and APA Claims.

Defendants dismiss Plaintiffs' APA and statutory claims regarding violations of 10 U.S.C. § 1107a because they claim: (1) Defendants are not in fact mandating EUA products, Opp. at 40; and (2) the statute merely imposes a "notification requirement," 24 i.e., a right to receive a package insert informing them of their statutory right to accept or refuse the EUA product, but that it does not actually grant a statutory right to refuse an EUA product. Plaintiffs addressed the first

<sup>&</sup>lt;sup>24</sup> Opp. at 40. Defendants also argue that Plaintiffs have "no private right of action" against the FDA for violations of 21 U.S.C. § 360bbb-3. Opp. a 41 (*citing Navy SEAL 1 v. Biden*, 574 F.Supp.3d 1124, 1130 (M.D. Fla. 2021) ("MDFL *Navy SEAL 1*"). Plaintiffs' right of action is provided by the APA, *i.e.*, they were harmed by the FDA's violations of their statutory rights, which provides a right of action for those harmed by agency action and do not have an express right of action under the statute violated. *See* 5 U.S.C. §§ 702, 704, 706(2)(C). The plaintiffs in the MDFL *Navy SEAL 1* case did not assert APA claims.

point—that Defendants have mandated EUA products—above in Section II.B. Plaintiffs and other class members have disciplined threatened with discharge for their refusal to take an EUA product, when it is undisputed that Defendants lacked an FDA-licensed product.

More importantly, however, from 2005 until July 2021, DOD and FDA held the position that EUA vaccines had to be voluntary. *See* 70 Fed Reg. 5452, 5455 (Feb.2, 2005) *See also* 2005 consent decree in *Doe v. Rumsfeld*, 2005 WL 774857 (D.D.C. Feb. 6, 2005) ("*Rumsfeld III*"), revising the Anthrax Vaccine Immunization Program to give personnel the option to refuse vaccination by prohibiting punishment for refusal of the vaccine.

Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

Optionality remained the DOD's consistent position until at least July 2021.<sup>25</sup> Defendants are estopped by the consent order in *Rumsfeld III* from arguing a contrary position, at least for those Plaintiffs and class members covered by that

<sup>&</sup>lt;sup>25</sup> Defendants' current interpretation of 10 U.S.C. § 1107a was first articulated in the July 6, 2021 Office of Legal Counsel Memorandum. *See* ECF 17-18 at 16-18. There, the DOD indicated that it "has understood section 1107a to mean that DOD may not require service members to take an EUA product," as reflected in DOD regulations. *See* Ex. 11 DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) (under the EUA statute, "potential recipients are provided an option to refuse administration," but "the President may... waive the option to refuse").

injunction.

Accordingly, Defendants' actions are an "unexplained departure" from decades-long "prior policy." Opp. at 38 (*quoting* Mot. at 42). The agencies "established practices" on informed consent are due greater deference than sudden, unexplained reversals because the long-standing and consistent refusal to exercise a claimed power (*i.e.*, to mandate an EUA product) is "significant in determining whether such a power was actually conferred." *W. Va. v. EPA*, 142 S. Ct. 2587, 2610 (2022) (citation and quotation marks omitted).

#### IV. PLAINTIFFS HAVE SUFFERED IRREPARABLE HARM.

Defendants contend that Plaintiffs cannot show that they will be irreparably harmed absent preliminary relief because Plaintiffs have failed to show that Defendants' actions "imminently threaten" to violate their rights, Opp. at 42; that a discharge alone cannot constitute irreparable harm, *id.* at 43; and that Defendants are not "forcing" Plaintiffs to be vaccinated. *Id.* at 44.

"The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67, 208 L.Ed.2d 206 (2020); *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 295 (5th Cir. 2012) ("This principle applies with equal force to the violation of RLUIPA rights because RLUIPA enforces First Amendment freedoms[.]"); *Holt v. Hobbs*, 574 U.S. 352, 357–58 (2015) (extending this principle to RFRA). As noted *supra*, II.E. p. 13, the religious objector suffers a

loss of free exercise when government "puts [the objector] to this choice." *Holt*, 574 U.S. at 361. Plaintiffs have shown in the preceding section that Defendant violations of First Amendment rights, as enforced through RFRA, are systemic and that they have already suffered the harms – and continue to do so – from these violations. *See supra* Section II.A.

In the PI Motion, Plaintiffs explained why a general discharge can also constitute irreparable injury under *Sampson v. Murray*, 415 U.S. 61 (1974), *see* Mot. at 43-44, where they are "discharge[d] without an individualized assessment of their fitness for continued service and for reasons unrelated to their ability to service," coupled with a discharge with a misconduct characterization that they will have to disclose along with their unvaccinated status, injuries that cannot be "address[ed] ... through post-discharge intra-service procedures." *Roe v. DOD*, 947 F.3d 207, 218 (4th Cir. 2020). Defendants have not refuted these arguments or shown that Plaintiffs are not facing imminent discharge.

## V. BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR GRANTING PRELIMINARY INJUNCTION.

Plaintiffs simply ask that this Court perform its assigned role, and duty, to interpret and enforce constitutional rights and "to determine whether those rights have been violated." *Emory*, 819 F.2d at 294. Here, there is no conflict between the public's "exceptionally strong interest in national defense," Opp. at 38, and Plaintiffs' constitutional rights. The most effective way to promote the public interest generally and the specific interest in strong national security is to enforce

Plaintiffs Constitutionally protected liberties by ceasing Defendants' systematic violations of constitutional rights that threaten national security. Defendants' imposition and enforcement of an unlawful vaccine mandate threatens to purge hundreds of thousands of service members, is destroying recruitment, and even threatens the viability of the AVF. *See* Mot., ¶ 8.

#### VI. CONCLUSION

This Court should grant the relief requested in the previously submitted Proposed Order.

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Respectfully submitted,

/s/ Dale Saran
Dale Saran, Esq.
MA Bar #654781
19744 W 116th Terrace
Olathe, KS 66061
Telephone: 480-466-0369
Email: dalesaran@gmail.com

/s/ Travis Miller
Travis Miller
Texas Bar #24072952
/s/ Brandon Johnson
Brandon Johnson, Esq.
DC Bar No. 491370
Defending the Republic
2911 Turtle Creek Blvd.,
Suite 300 Dallas, TX 75219
Tel. 214-707-1775
Email: bcj@defendingtherepublic.org

/s/ Simon Peter Serrano
S. Peter Serrano, Esq.
WA Bar #54769
5238 Outlet Dr.
Pasco, WA 99301
Telephone: 530-906-9666
Email: pete@silentmajorityfoundation.org

Attorneys for the Plaintiffs

#### **CERTIFICATE OF SERVICE**

This is to certify that on this 6th day of September, 2022 the foregoing Plaintiffs' Reply Brief was e-filed using the CM/ECF system.

Respectfully Submitted, /s/Brandon Johnson Brandon Johnson